Response document for MHRA public consultation on the proposal to make Maloff Protect available in Pharmacies
Ref: ARM93

ANNEX 1

Your details

Name: [redacted]

Position (if applicable): Superintendent Pharmacist (WR Evans Healthcare Ltd)

Organisation (if applicable): on behalf of PCT Healthcare Ltd and WR Evans Healthcare Ltd

Email: [redacted]

1. Do you consider that Maloff Protect should be available as a Pharmacy medicine?

Yes ☐ No ☐ Not sure ☑

Please provide any comments or evidence to support your response:

While we broadly welcome measures to increase the availability & accessibility of anti-malarials, we have concerns about whether reclassifying Atovaquone/Proguanil from Prescription Only Medicine (POM) to Pharmacy only (P) is the most appropriate way in which to do this.

We acknowledge that Atovaquone/Proguanil has a good safety profile but there is more to risk assessments for patients travelling than simply having anti-malarials that are safe & effective.

While the leaflet within the packaging does clearly state patients should also seek specialist advice regarding other risk factors & - apparently - there is space for the pharmacist to annotate the 'User Reminder Card' with contact details, we feel the provision of anti-malarials should be part of an all-encompassing risk assessment consultation. It is essential patients are made aware of any injections they also require & we are concerned the opportunity to give this information may be missed if Atovaquone/Proguanil was available without prescription.

We consider it to be more appropriate for patients to receive advice, information & any prophylaxis/immunisation required from a single source from a travel health specialist. In this way healthcare professionals can be certain the patient has been assessed in full & is aware of all risk factors for their planned travel.

Conducting travel risk assessment consultations, & preparing injection schedules, requires experience & training which is unlikely to be adequately covered in the manufacturer's training for the supply of Atovaquone/Proguanil.

Having sight of the manufacturer's proposed training material as part of this consultation would have been of assistance to us in making informed comments.

2. Do you have any specific comments on the leaflet or the label provided in the public reclassification report for Maloff Protect?

We do not have any specific comments in relation to the leaflet or the box.

It would have been helpful to have sight of the User Reminder Card & the proposed training materials as part of the consultation but it may be the case that these are still in development, pending confirmation of whether the POM to P reclassification application is successful.

Although the link & app accessed via the QR code is not yet available, we assume this will also be reviewed by MHRA prior to release & registered as a Medical Device if appropriate.

3. Do you have any other comments on the reclassification?

The consultation document indicates that the packs sizes that will be available are likely to be of 24 or 36. We have reservations about these as – depending on the retail price & the length of stay – patients may be inclined to purchase fewer tablets than they need to complete the course or have excess tablets left afterwards.

A lone traveller in a risk area for a fortnight would require 22 or 23 tablets. So a pack of 24 would give a spare in case of vomiting. Perhaps Glenmark's research / data indicates that this is likely to be the most common duration of travel?

Malarone & other POM generic Atovaquone/Proguanil are all presented in packs of 12, but at least when they are prescribed pharmacists are able to give the precise number required.

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes · Partially* · No ☑

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.